

Please type a plus sign (+) inside this box → 

Approved for use through 08/30/03. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

# TRANSMITTAL FORM

*(to be used for all correspondence after initial filing)*

		Application Number	10/712,678
		Filing Date	November 12, 2003
		First Named Inventor	Gene Michal
		Group Art Unit	3738
		Examiner Name	Alvin J. Stewart
Total Number of Pages in This Submission	268	Attorney Docket Number	50623.352

## ENCLOSURES (check all that apply)

<input checked="" type="checkbox"/> Deposit Account 07-1850 Authorization <input checked="" type="checkbox"/> Postage Paid Return Postcard <input type="checkbox"/> Response To Office Action <input type="checkbox"/> Amendment Transmittal Letter (in duplicate) <input type="checkbox"/> Statement of Common Ownership <input type="checkbox"/> Petition for Extension of Time ( months) (in duplicate) <input type="checkbox"/> Information Disclosure Statement ( pages) (in duplicate) with Form PTO-1449 ( pages) citing References <input checked="" type="checkbox"/> Express Mail Label No. EV 889007786 US <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) In/Formal ___ Sheets with Submission of Drawings Transmittal <input type="checkbox"/> Issue Fee Transmittal with PTO-85b (in duplicate) <input type="checkbox"/> Request for Continued Examination (RCE) Transmittal (1 page) (in duplicate) <input checked="" type="checkbox"/> Fee Transmittal (1 page) (in duplicate) <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) ___	<input type="checkbox"/> After Allowance Communication to Group <input checked="" type="checkbox"/> Appeal Brief (265 pages) <input type="checkbox"/> Notice of Appeal (in duplicate) <input type="checkbox"/> Reasons For Request of Pre-Appeal Brief Review <input type="checkbox"/> Request for Status of Application <input type="checkbox"/> Other:
Remarks		

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Squire, Sanders & Dempsey L.L.P. Zhaoyang Li, Ph.D., Reg. No. 46,872
-------------------------	---

Signature	
-----------	---

Date	July 10, 2007
------	---------------

## CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail in an envelope addressed to: Commissioner for Patents, Mail Stop Appeal Brief-Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date: July 10, 2007

Typed or printed name	Rebecca M. Klits
-----------------------	------------------

Signature		Date	July 10, 2007
-----------	---	------	---------------

EV889007786US

Express Mail No. EV 889007786US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In Re Application Of: Examiner: Alvin J. Stewart  
Gene Michal Art Unit: 3738  
Serial No: 10/712,678  
Filed: November 12, 2003  
For: Ethylene-Carboxyl Copolymers As  
Drug Delivery Matrices

Mail Stop Appeal Brief-Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

## **APPEAL BRIEF**

Dear Sir:

This Appeal Brief is submitted pursuant to receipt of an Advisory Action mailed on April 11, 2007, in which the examiner maintained his rejection of independent claims 44-54.

### REAL PARTY IN INTEREST

The real party in interest with regard to this appeal is Advanced Cardiovascular Systems Inc., a California corporation, having a place of business at 3200 Lakeside Drive, Santa Clara, California 95054. The original assignment to Advanced Cardiovascular system Inc. was recorded at Reel/Frame 011694/0183 on June 27, 2001. Effective February 13, 2007, Advanced Cardiovascular Systems Inc. changed its name to Abbott Cardiovascular Systems Inc.

### RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences related to or that might have any bearing, direct or indirect, on the Board's decision in this appeal.

### STATUS OF CLAIMS

Claims 44-54 are pending in the application.

Claims 44-54 are rejected and form the subject of this appeal.

Claims 37-49 were initially filed in this case as a divisional application of U.S. application No. 09/748,719, filed December 22, 2000, issued as U.S. Patent No. 6,824,559. Claims 37 and 44 are independent claims. Claims 38-43 depend from claim 37, and claim 45-49 depend from claim 44. In an office action mailed October 4, 2004 (**Evidence Appendix, "A"**), claims 37-49 were rejected as being obvious over U.S. Patent No. 6,379,379 to Wang ("Wang") (**Evidence Appendix, "B"**) in view of U.S. Patent No. 4,142,526 to Zaffaroni et al. ("Zaffaroni") (**Evidence Appendix, "C"**). Applicant responded on January 4, 2005, pointing out that Zaffaroni does not describe or teach (1) an ethylene-carboxylic acid copolymer and (2) a copolymer with 5-50 wt% of carboxylic acid monomer (**Evidence Appendix, "D"**). Applicants argued that claims 37-49 are non-obvious over Wang in view of Zaffaroni.

On March 22, 2005, the examiner issued another office action (**Evidence Appendix, "E"**), in which the examiner allowed claims 44-49, but again rejected claims 37-43 as being anticipated by U.S. Patent No. 6,738,661 to Nyhart, Jr. under 35 U.S.C. 102(e) ("Nyhart") (**Evidence Appendix, "F"**). The examiner argued that Medtronic describes a polymer coating composition having a heparin adduct and further comprising poly(ethylene glycol) chains. Applicants responded on June 29, 2005

(**Evidence Appendix, "G"**), pointing out that Nyart does not describe or teach (1) an ethylene-carboxylic acid copolymer and (2) a copolymer with 5-50 wt% of carboxylic acid monomer. Applicants argued that Nyart does not anticipate claims 37-43. On June 29, 2005, a notice of non-compliant amendment was mailed, indicating that the response filed by Applicants on June 22, 2005 fails to provide a list of claims and the claims were not presented in ascending numerical order (**Evidence Appendix, "H"**). Applicants addressed the non-compliance issues by a communication mailed on July 7, 2005 (**Evidence Appendix, "I"**).

On September 29, 2005, the examiner mailed an office action (**Evidence Appendix, "J"**), withdrawing the rejections of claims 37-43 over Nyart, but rejecting these claims as being anticipated by U.S. Patent No. 5,401,512 to Rhodes ("Rhodes") (**Evidence Appendix, "K"**) under 35 U.S.C. 102(b). Applicants responded on November 30, 2005, amending claim 37 to additionally recite "wherein the copolymer is a coating on an implantable substrate" (**Evidence Appendix, "L"**). Applicants pointed out that Rhodes describes "an orally administrable formulation for selectively administering the drug to the large intestine" but fails to teach or suggest all the limitations of Claim 37 and that claims 37-43 are thus allowable over Rhodes. On December 14, 2005, a notice of non-compliant amendment was mailed, indicating that the response filed by Applicants on November 30, 2005 fails to provide to a proper status identifier to the claims (**Evidence Appendix, "M"**). Applicants addressed the non-compliance issues by a communication mailed on January 6, 2006, in which Applicants also canceled claim 43 and added new claims 50-55 (**Evidence Appendix, "N"**).

On March 22, 2006, the examiner mailed a final office action (**Evidence Appendix, "O"**), allowing claims 44-54, and rejecting claims 37-42 and 55 as being anticipated by Rhodes under 35 U.S.C. 102(b). The examiner alleged that the limitation "wherein the copolymer is a coating on an implantable substrate" is functional and thus would not add patentability weight to the claims. Applicants responded on May 8, 2006, amending the claims to recite "a drug delivery coating on an implantable medical device" instead of "a drug delivery matrix" (**Evidence Appendix, "P"**). Applicants pointed out that Rhodes fails to provide a drug delivery coating. On May 25, 2006, the examiner mailed an advisory action (**Evidence Appendix, "Q"**), refusing to enter the

amended claims. On June 2, 2006, Applicants filed a supplemental response to final office action, canceling all the rejected claims, claims 37-42 and 55 (**Evidence Appendix, "R"**).

On August 24, 2006, the examiner mailed an office action (**Evidence Appendix, "S"**), rejecting claims 50-52 as indefinite, rejecting claims 44-46 and 53-54 as being anticipated by U.S. Patent No. 5,631,328 to Wang et al. ("Wang II") (**Evidence Appendix, "T"**) under 35 U.S.C. 102(b), and rejecting claims 47, 48 and 50-52 over Wang II in view of U.S. Patent No. 6,087,412 to Chabrecek et al. ("Chabrecek") (**Evidence Appendix, "U"**) and claim 49 over Wang II in view of U.S. Patent No. 4,729,914 to Kliment et al. ("Kliment") (**Evidence Appendix, "V"**) as being obvious under 35 U.S.C. 103(a). Applicants responded on November 7, 2006, pointing out that Wang II describe a composition that includes (a) an alpha-olefin, (b) an ester of alpha, beta-ethylenically-unsaturated carboxylic acid, and (c) a metal salt of acrylic or methacrylic acid but not a copolymer of an ethylene comonomer with a carboxylic acid comonomer (**Evidence Appendix, "W"**). Applicants further pointed that both Chabrecek and Kliment fail to provide a copolymer of an ethylene comonomer with a carboxylic acid comonomer. Applicants argued that claims 44-54 are allowable.

On February 12, 2007, the examiner mailed a final office action (**Evidence Appendix, "X"**), maintaining the rejections of claims as set forth in the Office Action mailed on August 24, 2006. The examiner further rejected claims 44-54 as failing to comply with the written description requirement. Applicants responded on March 21, 2007, in which Applicants amended the specification to make the claims to comply with the written description requirement but did not amend the claims. Applicants again pointed out that none of Wang II Chabreck and Kliment describe or teach a copolymer of an ethylene comonomer with a carboxylic acid comonomer. Applicants again argued that claims 44-54 are allowable.

On April 11, 2007, the examiner mailed an advisory action (**Evidence Appendix, "Y"**), maintaining the rejections of claims as set forth in the Final Office Action mailed on February 21, 2007.

Amendments in the response to Final Office Action filed on March 21, 2007 have been entered. Thus, claims 44-54 as pending on March 21, 2007, are the subject of this appeal.

## STATUS OF AMENDMENTS

As indicated above, amendments in the Response to Final Office Action filed January 8, 2007 and prior amendments have been entered and are before the Board.

## SUMMARY OF THE CLAIMED SUBJECT MATTER

The claimed invention relates to a method of coating an implantable medical device. Claim 44 is the sole independent claim, which succinctly set forth the invention:

44. A method of coating an implantable medical device, comprising:  
adding a copolymer of an ethylene comonomer with a carboxylic acid comonomer to a solvent system to form a composition;  
applying the composition to an implantable medical device; and  
allowing the solvent system to evaporate.

Support for claim 44 is found at least at page 3, line 21 to page 4, line 4; and page 17, line 21 to page 18, line 7 (Example 9) of the specification.

Claims dependent from claims 44 further define the scope of the invention in different aspects. The complete claim set as currently entered is provided in the **Claims Appendix**.

## GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues presented in this appeal are:

- (1) Whether claims 44-46 and 53-54 are anticipated by U.S. Patent No. 5,631,328 to Wang et al. ("Wang II") (**Evidence Appendix, "T"**) under 35 U.S.C. 102(b);
- (2) whether claims 47, 48 and 50-52 are obvious over Wang II in view of U.S. Patent No. 6,087,412 to Chabrecek et al. ("Chabrecek") (**Evidence Appendix, "U"**) under 35 U.S.C. 103(a); and
- (3) whether claim 49 is obvious over Wang II in view of U.S. Patent No. 4,729,914 to Kliment et al. ("Kliment") (**Evidence Appendix, "V"**) under 35 U.S.C. 103(a).

## ARGUMENT

(1). Claims 44-46 and 53-54 are allowable over U.S. Patent No. 5,631,328 to Wang II under 35 U.S.C. 102(b)

### A. The Law

Anticipation is established only when a single prior art reference discloses, expressly or under the principles of inherency, each and every element of a claimed invention. RCA Corp. v. Applied Digital Data Sys., Inc., 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). When the claimed invention is not identically disclosed in a reference, and instead requires picking and choosing among a number of different options disclosed by the reference, then the reference does not anticipate. Thus, the invention must have been known to the art in the detail of the claim; that is, all of the elements and limitations of the claim must be shown in a single prior reference, arranged as in the claim. See Karsten Mfg. Corp. v. Cleveland Gulf Co., 242 F.3d 1376, 1383, 58 USPQ2d 1286, 1291 (Fed. Cir. 2001); Akzo N.V. v. International Trade Commission, 808 F.2d 1471, 1480, 1 USPQ2d 1241, 1245-46 (Fed. Cir. 1986), cert. denied, 107 S.Ct. 2490 (1987); In re Arkley, 455 F.2d 586, 587-88, 172 USPQ 524, 526 (CCPA 1972).

### B. The Analysis

The examiner's rejection does not follow the guidelines provided by the Courts. Claim 44 defines a method of coating an implantable medical device. The method includes the acts of (1) adding a copolymer of an ethylene comonomer with a carboxylic acid comonomer to a solvent system to form a composition, (2) applying the composition to an implantable medical device, and (3) allowing the solvent system to evaporate.

In contrast, Wang II describes forming a composition of ionomers that can form a film (col. 6, lines 17-63). The composition can be formed of three monomers: (a) an alpha-olefin, (b) an ester of alpha, beta-ethylenically-unsaturated carboxylic acid (see col. 2, lines 55 and 56), and (c) a metal salt of acrylic or methacrylic acid (col. 2, lines 55-59; col. 4, line 59 through col. 5, line 63).

Therefore, Wang II does not describe forming a coating including a copolymer of an ethylene comonomer with a carboxylic acid comonomer. A person of ordinary skill in the art can readily appreciate that esters of a carboxylic acid and metal salts of a carboxylic acid are totally different chemical entities from the carboxylic acid.

In the Office Action mailed on February 12, 2007, the examiner states that Wang II reads on the claims because the two compounds mentioned in the claim are part of a copolymer (page 3, middle paragraph). Applicant respectfully fails to see the relevance of this statement. Applicant can certainly see that Wang II describes a copolymer. However, the copolymer described by Wang II is entirely different from the copolymer defined by claim 44 (see the discussion above).

In sum, claim 44 is not anticipated by Wang II under 35 U.S.C. §102(b). Claims 45, 46, 53 and 54 depend from claim 44 and are not anticipated by Wang II under 35 U.S.C. §102(b) for at least the same reason.

**(2) Claims 47, 48 and 50-52 are non-obvious over Wang II in view of Chabrecek under 35 U.S.C. 103(a)**

**A. The Law**

Claims are non-obvious if the claimed subject matter is more than a predictable use of prior art elements according to their established functions (see, KSR International Co. v. Teleflex, Inc., 550 U.S. \_\_\_, Slip Opinion No. 04-1350, page 13 (2007)).

Claims 47, 48 and 50-52 all depend from claim 44 and therefore all recite a copolymer of an ethylene comonomer with a carboxylic acid comonomer. Wang II fails to provide for this copolymer (see the discussion above). Chabrecek describes a macromer that include a segmented copolymer, which is an amide (col. 1, line 20 through col. 2, line 23). Chabrecek describes toluene as a solvent but does not describe a copolymer of an ethylene comonomer with a carboxylic acid comonomer. Therefore, Wang II and Chabrecek together do not teach the element "a copolymer of an ethylene comonomer with a carboxylic acid comonomer."

As mentioned previously, esters of a carboxylic acid and metal salts of a carboxylic acid are totally different chemical entities from the carboxylic acid. In addition, esters of a carboxylic acid and metal salts of a carboxylic acid have totally different physical and mechanical properties than the carboxylic acid. For example, as

an ordinary artisan would recognize, an ester of a carboxylic acid is more hydrophobic than the carboxylic acid. Conversely, a metal salt of the carboxylic acid is more hydrophilic than the carboxylic acid. A film formed of an ester of a carboxylic acid or a metal salt of a carboxylic acid would have totally different physical, mechanical, or drug release properties than a film formed of a carboxylic acid. A key aspect of the Wang II reference is to use a combination of an ester and metal salt of a carboxylic acid monomers for forming a film which has low haze (col. 1, lines 13-19), which attests to the different film properties different monomers in a polymer of the film can impart to the film. As such, to a person of ordinary skill in the art, a copolymer of an ethylene comonomer with a carboxylic acid comonomer as defined by any of claims 47, 48 and 50-52 is not a predictable variation of a copolymer formed of three monomers: (a) an alpha-olefin, (b) an ester of alpha, beta-ethylenically-unsaturated carboxylic acid, and (c) a metal salt of acrylic or methacrylic acid as described by Wang II.

Further, each of claims 47, and 50-52 includes limitations that carry additional patentability weight. Claim 47 further recites adding a therapeutic agent to the solvent system, and claims 50-55 require the carboxylic acid co-monomer content in the copolymer to be no less than 5% by weight and/or no more than 50% by weight.

In sum, claims 47, 48 and 50-52 are non-obvious over Wang II in view of Chabrecek under 35 U.S.C. 103(a)

**(3) Claim 49 is non-obvious over Wang II in view of Kliment under 35 U.S.C. 103(a)**

Claim 49 depends from claim 48, which recites a copolymer of an ethylene comonomer with a carboxylic acid comonomer. Claim 49 further requires the solvent system to further comprise a chlorinated solvent and a lower alcohol.

Wang II is discussed above. Kliment describes a copolymer that can be dissolved in a chlorinated solvent. However, Kliment does not describe a copolymer of an ethylene comonomer with a carboxylic acid comonomer. Therefore, Wang II and Kliment together do not teach the element, a copolymer of an ethylene comonomer with a carboxylic acid comonomer. As the above discussion shows, this copolymer is NOT a predictable variation of a copolymer formed of three monomers: (a) an alpha-olefin, (b) an ester of alpha, beta-ethylenically-unsaturated carboxylic acid, and (c) a metal salt of

acrylic or methacrylic acid as described by Wang II. Accordingly, claim 49 is non-obvious over Wang II in view of Kliment under 35 U.S.C. §103(a).

### CONCLUSION

The examiner has failed, as a matter of law, to set forth a case of anticipation of claims 44-46 and 53-54 by Wang II under 35 U.S.C. 102(b).

The examiner has failed, as a matter of law, to set forth a case of obviousness of claims 47, 48 and 50-52 under 35 U.S.C. 103(a) over Wang II in view of Chabrecek.

The examiner has failed, as a matter of law, to set forth a case of obviousness of claims 49 under 35 U.S.C. 103(a) over Wang II in view of Kliment.

Appellants therefore respectfully request that the Board reverse the rejections and order the application to be passed to issue.

Date: July 10, 2007

Squire, Sanders & Dempsey L.L.P.  
One Maritime Plaza, Suite 300  
San Francisco, CA 94111  
Telephone (415) 393-9885  
Facsimile (415) 393-9887

Respectfully submitted,



Zhaoyang Li, Ph.D., Esq.  
Reg. No. 46,872

# CLAIMS APPENDIX

**WHAT IS CLAIMED:**

1-43. (Canceled).

44. (Previously presented) A method of coating an implantable medical device, comprising:

    adding a copolymer of an ethylene comonomer with a carboxylic acid comonomer to a solvent system to form a composition;

    applying the composition to an implantable medical device; and  
    allowing the solvent system to evaporate.

45. (Previously presented) The method of claim 44, wherein the carboxylic acid comonomer is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.

46. (Previously presented) The method of claim 44, wherein adding the copolymer to the solvent system further comprises neutralizing the copolymer in a volatile or a non-volatile base and dispersing the copolymer in water and/or a co-solvent.

47. (Previously presented) The method of claim 44, further comprising adding a therapeutic agent to the solvent system.

48. (Previously presented) The method of claim 44, wherein the solvent system comprises toluene.

49. (Previously presented) The method of claim 48, wherein the solvent system further comprises a chlorinated solvent and a lower alcohol.

50. (Previously presented) The method of claim 44, wherein the carboxylic acid co-monomer has a content in the copolymer no less than 5% by weight.

51. (Previously presented) The method of claim 50, wherein the carboxylic acid co-monomer has a content in the copolymer no more than 50% by weight.

52. (Previously presented) The method of claim 44, wherein the carboxylic acid co-monomer has a content in the copolymer no more than 50% by weight.

53. (Previously presented) The method of claim 44, wherein the co-polymer is ethylene acrylic acid.

54. (Previously presented) The method of claim 44, wherein the device comprises a stent.

# EVIDENCE APPENDIX

Attached hereto are the following:

- (A) Office action mailed October 4, 2004;
- (B) U.S. Patent No. 6,379,379 to Wang ("Wang ");
- (C) U.S. Patent No. 4,142,526 to Zaffaroni et al. ("Zaffaroni");
- (D) Response to Office Action filed on January 4, 2005;
- (E) Office Action mailed on March 22, 2005;
- (F) U.S. Patent No. 6,738,661 to Nyhart, Jr. ("Nyhart");
- (G) Response to Office Action mailed on June 29, 2005;
- (H) Notice of non-compliant amendment mailed on June 22, 2005;
- (I) Response to Notice of non-compliant amendment mailed on July 7, 2005;
- (J) Office Action mailed on September 29, 2005;
- (K) U.S. Patent No. 5,401,512 to Rhodes ("Rhodes");
- (L) Response to Office Action mailed on November 30, 2005;
- (M) Notice of non-compliant amendment mailed on December 14, 2005;
- (N) Response to Notice of non-compliant amendment mailed on January 6, 2006;
- (O) Final Office Action mailed on March 22, 2006;
- (P) Response to Final Office Action mailed on May 8, 2006;
- (Q) Advisory Action mailed on May 25, 2006;
- (R) Supplemental Response to Final Office Action mailed on June 2, 2006;
- (S) Office Action mailed on August 24, 2006;
- (T) U.S. Patent No. 5,631,328 to Wang et al. ("Wang II");
- (U) U.S. Patent No. 6,087,412 to Chabrecek et al. ("Chabrecek");
- (V) U.S. Patent No. 4,729,914 to Kliment et al. ("Kliment");
- (W) Response to Office Action mailed on November 7, 2006;
- (X) Final Office Action mailed on February 12, 2007; and
- (Y) Advisory Action mailed on April 11, 2007.